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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0539]

Establishing a Docket for the Development of Plasma Standards Public Workshop; Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments on the August 31 and September 1, 2004, public workshop entitled "Development of Plasma Standards" (the workshop). We are opening the docket to gather additional information from interested parties on the subjects of plasma collection, freezing, and storage, and for interested parties to provide comments on the presentations and discussions that took place during the workshop.

DATES: Submit written or electronic comments on the workshop, related regulatory and scientific issues, and comments on information submitted to the docket by other interested parties by [*insert date 6 months after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments and information regarding the workshop to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–1448. Submit electronic comments or information to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic and other access to the slide presentations and transcripts from the workshop.

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FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2004 (69 FR 48250), we published a notice to announce a public workshop entitled "Development of Plasma Standards." On August 31 and September 1, 2004, we held the workshop to address regulatory and scientific issues about currently licensed plasma products and unlicensed recovered plasma that is fractionated into both injectable and non-injectable products. The workshop covered a broad range of topics. A major objective of the workshop was to assist FDA in the development of plasma standards that would address concerns encountered over the years with regard to the preparation, storage, shipment, and use of plasma for both transfusion and the manufacture of plasma derived blood products such as Factor VIII and Immune Globulin Intravenous. Another objective was to gather information on current industry practices that are in place for the manufacture of plasma. At the end of the workshop, we invited written comments from workshop participants to gather additional public information on the subject of plasma freezing and storage.

We have established this docket to encourage interested parties to continue to provide information about suggested plasma standards, comments on the workshop, and comments on information submitted to the docket by other interested parties. We also request that those who have already submitted written comments and information to FDA resubmit the same comments to the docket to ensure their adequate consideration since this information was

previously submitted to the docket. This notice will also be posted at *http://www.fda.gov/cber/minutes/workshop-min.htm.*

Comments submitted to the docket will assist us in determining the need for and feasibility of establishing new standards for currently licensed plasma products, including time to freezing, freezing and storage temperatures, and shipping temperatures, among other issues. We may also consider this information in preparing any future additional standards for recovered plasma.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of this notice, the slide presentations and transcripts from the workshop, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the slide presentations at *http://www.fda.gov/cber/summaries.htm* and the transcripts of the workshop at *http://www.fda.gov/cber/minutes/workshop-min.htm.*

Dated: 12/15/04
December 15, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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